

**REMARKS**

Claims 1-14, 17-21 and 43 are pending, claims 1 and 43 have been amended, antecedent basis for which is found, for instance, at paragraph [0039], claims 13-16 and 22-42 have been canceled.

The double patenting rejections are being maintained in order to be finally resolved at such point where there is an indication of allowable subject matter, at which time, Applicant will consider and file any terminal disclaimer that is deemed proper.

The rejections under Sections 102 and 103 based on Hustead et al. ('970), and under Section 103 based on Yamanaka et al ('497), are respectfully traversed.

As mentioned previously, Hustead et al. appears to be cited largely for teaching a pH of up to 8.0, in the course of providing local anesthetics. Though NaOH is mentioned in the reference, it is clearly used in a very different manner and for very different purposes than is presently described and claimed.

As also mentioned previously, Yamanaka et al. is cited for teaching a medicated plaster containing an active agent and a basic substance (e.g., sodium hydroxide or potassium hydroxide) to keep a pH of 7 or higher. As described previously, the reference also requires the presence of an acid to maintain the system during storage, and, in turn, nothing in the reference suggests the use of an enhancing and/or a neutralizing amount of a hydroxide-releasing agent.

With regard to both rejections, the current Office Action appears to rely on essentially one or both of the same two premises, both of which Applicant would rebut. First, it asserts that

an “intended use must result in a structural difference” in the claim itself, and second, that the mention of a pH of around 7 or 8, anywhere in a reference, is somehow “close enough” to establish a *prima facie* case of obviousness, with regard to the different, and considerably higher, range and overall composition as claimed.

With regard to the “structural difference”, and again in the interest of facilitating the prosecution of this application, Applicant has amended the claims in order to provide further attributes of the composition, and in turn, to further distinguish the cited art.

With regard to the “close enough” position set forth in the Action, Applicant would assert that this position becomes all the more untenable, and its weaknesses all the more apparent, when considered in view of the claims as amended above .

Applicants have made these amendments solely to advance prosecution of the present application and to obtain allowance at the earliest possible date. Accordingly, no admission may be inferred from these amendments. Applicants expressly reserve the right to pursue the originally filed claims in the future. Additionally, Applicants submit that the amendments made herein introduce no new matter. The following remarks are respectfully submitted.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested. The Commissioner is hereby authorized to charge any additional fees required to Deposit Account No. 061910.

Respectfully submitted,

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